

IN THE MATTER OF Patent Application No. US 10/560,954
in the name of Brian David Owen OWEN-SMITH

DECLARATION

I, Jonathan G. Hooker, Fellow of the Royal College of Obstetricians and Gynaecologists (FRCOG), of Western Sussex Hospitals NHS Trust, St Richard's Hospital, Spitalfield Lane, Chichester, West Sussex, PO19 6SE, United Kingdom, do solemnly and sincerely declare as follows:

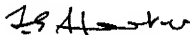
1. I am a consultant obstetrician and gynaecologist and a Fellow of the Royal College of Obstetricians and Gynaecologists. My curriculum vitae is attached.
2. I have been asked to comment on the subject matter of US Patent Application No. 10/560,954. My initial thoughts were as set out in my letter to Dr Owen-Smith 12th December 1997 in which I made the point that I did not think his observations of salivary urate in one patient with pre-eclampsia were significant. My authority for this was found in my reference which I sent with the letter (Medical Disorders in Obstetric Practice, Editor Michael de Swiet Third Edition 1995).
3. The rise in plasma urate seen in patients with pre-eclampsia is usually taken as an indication of impaired renal function, a feature of pre-eclampsia which is the cause of proteinuria. However it is also accepted in obstetric practice that elevated plasma urate levels per se do not influence the management of pre-eclampsia. Blood investigations including plasma urate levels are always used with caution and taken in context with other clinical symptoms and signs.
4. It is standard teaching in obstetrics (see de Swiet) that raised plasma urate is due to impaired renal function and reduced excretion of uric acid.
5. Conversely, in obstetrics uric acid is not considered to be associated with changes in purine metabolism.

6. Blood urate levels are routinely requested as part of the biochemical investigations into pre-eclampsia. Blood urate is used as an adjunct to diagnosis along with blood pressure measurement, quantification of proteinuria and other investigations including those for fetal wellbeing. No additional information would have thought to be gained by measuring urine or salivary uric acid levels.

7. I thought that salivary urate may well have been investigated before as an alternative to blood urate in other conditions, but I didn't think that it was relevant to the pathogenesis of pre-eclampsia for the reasons given above. It had never been part of routine obstetric care in pre-eclampsia to request salivary urate levels.

8. My knowledge of gout is limited. It is a condition which occurs in older males and is caused by uric acid crystals forming in joints such as the big toe. Gout does not occur in women of childbearing age including those with pre-eclampsia and I do not see the connection with middle aged men. Therefore, studies relating to changes in purine metabolism and urate levels in patients with gout would not have been significant.

9. When Dr Owen-Smith presented his initial finding to me, I discussed Dr Owen-Smith's finding with other colleagues in obstetrics who were somewhat sceptical concerning the use of salivary urate measurement in pre-eclampsia yet, personally, I was prepared to support his work as it has evolved.



J.G. Hooker FRCOG

Consultant Obstetrician & Gynaecologist



Date

Abbreviated Curriculum Vitae

Mr Jonathan G Hooker

Address: Department of Obstetrics and Gynaecology
St Richard's Hospital
Chichester
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Born 7th February 1949.

Undergraduate medical training at Cambridge University (BA 1971, MA 1974)
and The Middlesex Hospital, London (Qualified MB. B.Chir 1974).

General postgraduate training in several different hospitals in the UK 1974-1979.

3 year registrar rotation in obstetrics and gynaecology in Birmingham 1979-1982.

Qualified MRCOG 1982.

Trainee Fellow in Perinatal Medicine UCH, London 1982-1984.

Senior registrar obstetrics and gynaecology UCH, London 1984-1988.

Appointed consultant in obstetrics and gynaecology St Richard's Hospital, Chichester 1988.

Proceeded to FRCOG 1992.

Interests include maternal and fetal medicine. Currently responsible for management of pregnancies complicated by diabetes.

Several publications on topics mainly related to perinatal medicine.

Increasing management responsibilities at St Richard's include role as Clinical Director for Women and Children's services and (currently) Chairman of the senior medical staff committee.